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X. SAFETY AND EFFECTIVENESS SUMMARY (SMDA Requirements)

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Establishment Registration Number:	2021898
Address of Manufacturer:	Medtronic Neurosurgery (formerly Medtronic PS Medical) 125 Cremona Drive Goleta CA, 93117 (805) 968-1546 ext. 1770 Fax: (805) 968-9336
Contact Person:	Jeffrey Henderson
Date:	June 29, 2001
Trade or Proprietary Name:	Medtronic PS Medical STRATA Valves
Common usual or Classification Name:	Central Nervous System Fluid Shunts and Components, 21 CFR 882.5550

Predicate Device Identification:

1. Johnson & Johnson Hakim Programmable Valve System (K974739), Johnson & Johnson Hakim Micro Programmable Valve System (K980778). Substantial equivalence is based upon materials, design, performance specifications and intended use.
2. Sophysa Pressure Adjustable Valve System (K992465). Substantial equivalence is based upon design, performance specifications and intended use.
3. Medtronic PS Medical Delta-CSF Flow Control Valve (K902783). Substantial equivalence is based upon materials, performance specifications, design and intended use.
4. Medtronic PS Medical BioGlide CSF Flow Control Shunt Kit (K951258). Identical material and manufacturing process used for surface modification of the product

Description:

The STRATA™ Valve incorporates a ball and cone pressure valve in series with a normally closed siphon control mechanism. This combination enables the valve to maintain intraventricular pressure (IVP) within a normal physiological range, regardless of a patient's CSF flow requirements or body position.

Similar to the Hakim Programmable Valve and the Sophysa Pressure Adjustable Valve, the STRATA™ Valve incorporates the following features: (1) valve mechanism (spring biased ball in cone/seat), (2) 316L Stainless Steel spring coils for pressure flow regulation, (3) internal magnet, (4) valve element (ruby), (5) outer jacket (silicone elastomer). Additionally, the STRATA™ Valve incorporates a tamper-resistant internal dis-adjustment mechanism to prevent extreme changes in pressure (i.e., from the highest to the lowest settings) and a strong return spring to stabilize the rotor.

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The STRATA Valve is available with the BioGlide surface modification, identical to that reviewed under K951258. The product is also provided as part of a shunt configuration equivalent to that reviewed under K900676 and K951258. The shunt consists of the valve and a proximal and distal catheter, equivalent to those reviewed under K792007 and K792005.

Intended Use:
The STRATA™ Valve is a shunt component designed to provide continued Cerebrospinal Fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special magnetic adjustment tool. The tamper resistant design helps ensure that the valve's performance level is not inadvertently changed.

Intended Use Predicate Device:
Hakim Programmable Valve
A shunt component designed to provide continued Cerebrospinal Fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or peritoneal cavity. The design allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special valve programming unit.

Sophysa Pressure Adjustable Valve System
An implantable device designed for the treatment of hydrocephalus in adult and pediatric patients by shunting, thereby providing continuous controlled intraventricular pressure and CSF drainage from the cerebral ventricles. Intraventricular pressure is maintained at a constant level by the device's ball in cone valve seat design, and the valve is pressure adjustable transcutaneously.

Delta Valve
A shunt component designed to provide continued Cerebrospinal Fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or peritoneal cavity with a siphon control component to minimize the influence of negative hydrostatic pressure caused by the vertical siphon effect of the distal catheter, thereby minimizing over-drainage of the ventricles of the brain which result from a siphon condition.

Technological comparison: The STRATA™ Valve is equivalent to the Hakim Programmable Valve, Sophysa Pressure Adjustable Valve, Delta Valve and BioGlide CSF Flow Control Shunt Kit in components, materials, construction and performance specifications. All components have been deemed biocompatible and chemically acceptable and are, thus, safe and effective for the valve's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Jeffrey Henderson
Vice President, Quality
and Regulatory Affairs
Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117

Re: K012052
Trade/Device Name: Medtronic Strata™ Valve
Regulation Number: 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: November 8, 2001
Received: November 13, 2001

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: STRATA™ Valve 510(k) Number (if known): K012052

"The STRATA™ Valve is a shunt component designed to provide continued Cerebrospinal Fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or peritoneal cavity. The design allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special magnetic adjustment tool."

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012052

Over the Counter Use:____
or
Prescription Use: X
(Per 21 CFR 801.109)

(optional format 1-2-96)